

memorandum

DATE: August 19, 1998

REPLY TO: Office of Environmental Policy and Assistance (EH-41):Bascietto:6-7917
ATTN OF:

SUBJECT: **ECOLOGICAL RISK ASSESSMENT GUIDANCE FOR SUPERFUND: PROCESS FOR DESIGNING AND CONDUCTING
ECOLOGICAL RISK ASSESSMENTS; INTERIM FINAL**

TO: Distribution

**PURPOSE
OF THIS
MEMORANDUM** To notify DOE elements of the availability of the Environmental Protection Agency's (EPA) guidance for designing and conducting an ecological risk assessment (ERA) performed under the authority of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA); to highlight some of its key components; and to identify how interested parties can obtain the interim final guidance and other ERA-related information.

BACKGROUND A significant component of a CERCLA remedial investigation/feasibility study (RI/FS) is the baseline risk assessment, which consists of a human health risk assessment and an ERA. *Ecological Risk Assessment for Superfund: Process For Designing and Conducting Ecological Risk Assessments* (Interim Final), June 1997, describes an overall, step-by-step process by which an RI/FS ERA is designed and executed. Although this guidance furnishes EPA's most recent approach on **designing** and **conducting** an ERA, users should continue referring to *Risk Assessment Guidance for Superfund, Volume II, Environmental Evaluation Manual* ("RAGS II") (EPA/540/1-89/001) for fundamental ERA information and concepts (e.g., factors influencing and effects of contaminants on ecosystems). It should be noted that although the guidelines presented in this document are not enforceable regulations, EPA believes they furnish a technically valid and defensible approach for conducting ERAs, deviation from which requires clear documentation of the alternate process, including process design and interpretation of the results.

**KEY
ELEMENTS
OF THE
GUIDANCE** Although consistent with EPA's *Guidelines for Ecological Risk Assessment* [May 14, 1998 *Federal Register* (63 FR 26846)] and *Framework for Ecological Risk Assessment* (EPA/630/R-92/001; February 1992), this guidance separates the three primary phases of an ERA into a CERCLA-specific, eight-step process. Before introducing the eight-step ERA process, it is important to highlight a significant new ERA component established therein--scientific/ management decision points (SMDPs). SMDPs are intended to ensure that site management decisions are made quickly, without the need for repeated studies, and entail meetings between the risk manager and the multi-disciplinary risk assessment team. SMDPs are used throughout the ERA process to evaluate and approve **or** redirect ERA-related efforts by facilitating consensus from all involved parties for the selected path forward.

**STEPS
1 and 2** Relative to the eight-step ERA process itself, Steps 1 and 2 are intended to expedite a risk manager's determination of the need to halt or continue the ERA by screening for ecological risks. Step 1 begins with the development of a screening-level conceptual model. When considering screening-level exposure estimates (Step 2), EPA's guidance recommends evaluating only those previously-identified exposure pathways that are complete, and using the highest measured or estimated on-site contaminant concentration or EPA's recommended exposure assumptions (presented therein) if site-specific information is lacking.

Screening-level risk values calculated during Steps 1 and 2 are used to decide whether the potential for ecological impacts exists, resulting in one of only three possible decisions: (1) Information is adequate to conclude ecological risks are negligible and the ERA process ends here; (2) Information is inadequate to make a decision, or (3) Information indicates a potential adverse ecological effect exists and, therefore, continue. Regardless of which decision is reached, it is ultimately made, documented, and communicated to EPA by the DOE risk manager (collaboratively with the risk assessment team) during the first SMDP.

STEP 3	During Step 3 (problem-formulation), the goals, breadth, and focus of the baseline ERA, as well as the assessment endpoints or specific ecological values to be protected, are established. Step 3 culminates with an SMDP that formalizes an agreement on the contaminants of concern, assessment endpoints, exposure pathways, and questions portrayed in the conceptual model, which is designed to prevent returning to the problem-formulation step due to changing personnel and preferences.
STEP 4	During the “Study Design and Data Quality Objectives Process” (Step 4), measurement endpoints, which (as used in this guidance) include measures of exposure as well as measures of effect, are established, integrated into, and complete the conceptual model. Step 4 concludes with an SMDP, during which the ecological risk assessor and risk manager reach agreements on selection of measurement endpoints, site investigation methods, and data reduction and interpretation techniques.
STEP 5	The primary purpose of Step 5 -- Field Verification of Sampling Design -- is to verify that field study-targeted species are present and collectable in sufficient numbers or total biomass to meet site-specific data quality objectives. It terminates with an SMDP during which the Work Plan (WP) and Sampling and Analysis Plan (SAP) are signed.
STEPS 6 and 7	Signature of the WP and SAP denote the beginning of the Site Investigations (SI) and Analysis Phase and Risk Characterization (Steps 6 and 7), which entails implementing the previously designed study. The SI and analysis/risk characterization phases culminate with an SMDP only if alterations to the WP or SAP become necessary.
STEP 8	Risk management integrates the results of the risk characterization with other considerations and, at CERCLA sites, is used in conjunction with CERCLA’s nine criteria in developing and justifying the preferred remedial alternative. Risk management decisions are identified for stakeholder comment in the Proposed Plan and finalized (“selected”) in the executed Record of Decision during the final SMDP.

AVAILABILITY OF ECOLOGICAL RISK GUIDANCE	Copies of the subject guidance can be obtained from the National Technical Information Service (NTIS) in Springfield, Virginia at (703) 487-4650 (Order No. PB97-963-211). Also, users are encouraged to access the “DOE Office of Environmental Policy and Assistance Dose and Risk Resources Web Page” (http://tis-nt.eh.doe.gov/oepa/risk/) for guidance, policy, and technical assistance on ecological, radiological, and dose and risk issues relevant to DOE Program and Operations Offices.
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ADDITIONAL INFORMATION	<p>Questions concerning the interim draft or the information presented herein may be directed to John Bascietto of my staff by:</p> <ul style="list-style-type: none"> • Calling at (202) 586-7917, • Faxing messages to (202) 586-3915, or • Communicating electronically, via Internet, to “john.bascietto@eh.doe.gov”.
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